



Bergen University

Indication and treatment of adult spinal deformity

The INTRAKS-study



26.08.2020



INQUIRY TO PARTICIPATE IN A RESEARCH PROJECT

Indication and treatment of adult spinal deformity, INTRAKS-study.

This is an inquiry for you to participate in a research project to investigate treatment methods, results and complications regarding correctional surgery to the spine. There are three axes of the study:

- 1: Patients operated in the past five years.
- 2: Correctional surgery with 12 months follow up.
- 3: Non-surgical treatment with 12 months follow up.

The 1. axis is a study where we look back in time; we search the journal for patients that underwent spinal correctional surgery in the past five years in Ullevål- or Haukeland University Hospital. You are chosen because you underwent such an surgery in the past five years in one of the two Hospitals.

The 2. axis of the study looks forwards in time. You are chosen because you fulfill the inclusion criteria by your clinical consultation in the hospital that means that you have a deformity of your spine that can be corrected.

The 3. axis of the study looks forwards in time. You are chosen because you fulfill the inclusion criteria by your clinical consultation in the hospital, that means that you have a deformity of your spine that can profit from non-surgical treatment, but we are not sure of the effect of the treatment.

The personal data will be stored anonymous on a research server at Haukeland University Hospital and/or "Service for Sensitive data" (TSD, Oslo University). The patient is given a number. The list that can identify you is cryptic and stored in a safe.

WHAT DOES IT MEAN FOR YOU?

The investigators intend to compare the degree of x-ray correction before and after treatment, investigate the MRI and CT scans to look for spinal- or foraminal-stenosis, fusion after surgery and to examine for possible osteoporosis before surgery or non-surgical treatment (only 2. axis of the study), collect demographic data, register surgical techniques, complications and control the outcome in clinical controls after 12 months and questionnaires at the homepage "intraks.org" (only 2. axis of the study).

In the project there will be gathered and registered information about you.

In the axis 1 of the study; you will have to fill out the questionnaire send to you by mail or made available for you in the homepage intraks.org, your x-rays before and after surgery will be evaluated.

In the 2. and 3. axis of study; information about you will be registered from the national quality register for spinal surgery in Norway, osteoporosis examination and measurements on x-rays before and 12 months after surgery. There will be additional questionnaire. The MRI and CT scans will be examined for spinal and foraminal stenosis and degree of fusion. The patients participating in the 3. axis of the study will follow a tailored training program for 12 months.

Information will be gathered from the patient journal; demographic data, age, sex, BMI, mother language, nationality, race, employment. Perioperative registration; smoking, diabetes, comorbidities, ASA, prior surgery, surgical procedure, perioperative complications, surgical revisions.

POSSIBLE ADVANTAGES AND DISADVANTAGES

There will be no changes to the planed treatment; there will be a closer follow up. Complications can be detected earlier and treated if necessary. If osteoporosis is detected, it will be treated accordingly.

THE PARTICIPATION IS VOLUNTARY AND YOU MIGHT WITHDRAW YOUR INFORMED CONTENT AT ANY TIME

The participation is voluntary. If you choose to participate you need to sign the informed contend at the last page. You might at any time withdraw your informed contend, no reason attached. It will have no influence on your further treatment. If you withdraw from the project, you can demand to have all collected data erased, if the data is not already in use for analysis or scientific publications. If you choose to withdraw from the project or have any further questions regarding the project, you can

WHAT HAPENDS TO YOUR PERSONAL DATA?

Your registered personal data will only be used as described. You have the right to access the personal information and a right to correct eventual errors in the stored data. You are also available to evaluate the security measures made to handle and store your personal data.

The information will be stored anonymous; a code will connect the information stored to you on a name list. It is only the project leader that can access the identification list.

The project manager is responsible for the daily operation of the research project and a safe storage of your personal data. The personal data will be made anonymous or erased 15 years after ending the project. Extended follow up time or later studies might follow, that means that we can follow up the patients after for example two or five years.

INSURANCE

There will be no change in the treatment, only the follow up and controls will be intensified. The non-surgical patients will be training according to the tailored program.

EXCHANGE OF PERSONAL DATA WITH OTHER PARTIES

By confirming the informed content, you agree the exchange of anonymous data; demographic data; age, sex, BMI, mother language, nationality, race, employment. Perioperative registration; smoking, diabetes, comorbidities, ASA, prior surgery, surgical procedures, complication,, x-rays before and after surgery or non-surgical treatment, DEXA, MRI and CT and the results of the PROMS can be exchanged with our cooperative partners at the Kyoto University Hospital in Japan and in Sweden Skåne University Hospital and Örebro University Hospital. This might be countries that do not satisfy European personal law. The data cannot be traced back to you; the code that identifies you will not be handed out.

We will use TSD for data exchange with our Swedish and Japanese cooperating parties. It is highly secure and cryptic, developed by Oslo University. It makes data sharing and statistical analysis much easier.

LATER PROJECTS

We can contact you again for long term follow up after several years.

APPROVAL

The project is approved by the Regional comity for medical scientific research, (2017/1378/1379.

In regard of the new personal information law; the sponsor Bergen University/Haukeland University Hospital and the project leader have the responsibility to ensure the legal use of your information. This project has a legal base according to the EU privacy regulation article 6 no. 1a and article 9 no. 2a and your informed content.

Informed consent to participate in the project

CONTACT INFORMATION

For any questions regarding the project, please contact, the study coordinator Oslo University Hospital ... or the study coordinator Haukeland University Hospital Data protection officer in the institution is ...

I AM WILLING TO PARTICIPATE IN THE PROJECT

Place and date

Participant signature

Participant name in capital letters

